K051551

JUN 28 2005

2005.6.8

SMDA 510(k) SUMMARY
SMALL INTESTINAL VIDEOSCOPE SYSTEM

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR, Part 807, Subpart E, Section 807.92.

1. GENERAL INFORMATION

Applicant	Aizu Olympus Co., Ltd 500 Aza Muranishi Ooaza Niidera, Monden-machi Aizuwakamatsu-shi, Fukushima, JAPAN 965-8520 Establishment Registration No.: 9610595
Submission Correspondent	Akiko Fukagawa Olympus Medical Systems Corp. 2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan Phone: +81-426-2891 Fax: +81-426-3174 E-mail: akiko_fukagawa@ot.olympus.co.jp Establishment Registration No.: 8010047
Official Correspondent	Laura Storms-Tyler Director, Regulatory Affairs and Quality Assurance Olympus America Inc. Two Corporate Center Drive, Melville, NY 11747-9058 Phone: 631-844-5688 Fax: 631-844-5554 Establishment Registration No.: 2429304

2. Device Identification

Trade Name:	SMALL INTESTINAL VIDEOSCOPE SYSTEM
Common Name:	Small Intestinal Videoscope
Regulation Number:	21CFR 876.1500/876.5980
Regulation Name:	Endoscope and accessories/Gastrointestinal tube and accessories
Class:	II
Product Code:	78 FDA/KNT

3. Predicate Device

The following listed devices are considered as predicate devices in consideration of their characteristics, and the following table shows their regulatory histories.

Model	510(k) #	Manufacturer	Class	Product Code
PCF-160AL/I	K001241	Olympus Optical Co., LTD	II	78 FDF
XSIF-1TQ140A Small Intestinal Videoscope	K031256	Olympus Opt-electronics Co., LTD	II	78 FDA / KOG
Fujinon Double Balloon Enteroscopy System	K040048	Fujinon, Inc.	II	78 FDA / KNT

4. Device Description

The subject device, Small I[illegible] Videoscope system, is [illegible]gned for endoscopy and endoscopic surgery within the small intestine.

The subject device utilizes sequential deployment of two balloons, one attached to an gastrointestinal [illegible]ment of the endoscope well within the small intestine. The subject device can access through the small intestine via either oral or anal introduction.

5. Intended Use of the device

SMALL INTEST[illegible] COPE SYSTEM

This system is [illegible] of the small intestinal videoscope and the other ancillary equipment. The small intestinal scope has been designed to be used with the Olympus Video System Center, light source, endoscope balloon controller, splinting tube, balloons, documentation equipment, video monitor, electrosurgical unit, endo-therapy accessories such as biopsy forceps and other ancillary equipment for endoscopy and endoscopic surgery within the upper and lower digestive tract including the esophagus, stomach, duodenum, small intestine and colon, by either oral or anal insertion.

6. Comparison of Technological Characteristics

Below is the comparison table between the subject devices and predicate device.

COMPARISON OF SPECIFICATIONS (With K001241 and K031256)
MODEL: XSIF-160DB(Subject Device) vs. XSIF-1TQ140A and PCF-160AL/I(Predicate Devices)

Specifications	XSIF-160DB (Subject Device)	XSIF-1TQ140A (Predicate Device)	PCF-160AL/I (Predicate Device)
Field of View	140°	140°	140°
Depth of Field	3~100 mm	3~100 mm	3~100 mm
Direction of View	0° Forward Viewing	0° Forward Viewing	0° Forward Viewing
Outer Diameter of Distal End	φ 9.2 mm	φ 10.9 mm	φ 11.3 mm
Outer Diameter of Insertion Tube	φ 9.2 mm	φ 11.3 mm	φ 11.5 mm
Working Length	2000 mm	2350mm	1680mm (L) 1330mm (I)
Inner Diameter of Instrument Channel	φ 2.8 mm	φ 3.7mm	φ 3.2 mm

COMPARISON OF SPECIFICATIONS(With K040048)

MODEL: XSIF-160DB(Subject Device) vs. EN-450P5/20(Predicate Device)

Specifications	XSIF-160DB (Subject Device)	EN-450P5/20 (Predicate Device)
Field of View	140°	120°
Depth of Field	3~100 mm	5~100 mm
Direction of View	0° Forward Viewing	0° Forward Viewing
Outer Diameter of Distal End	φ 9.2 mm	φ 8.5 mm
Outer Diameter of Insertion Tube	φ 9.2 mm	φ 8.5 mm
Inner Diameter of Instrument Channel	φ 2.8 mm	φ 2.2 mm

MODEL: XST-BY(Subject Device) vs. TS-12140(Predicate Device)

Specifications	XST-BY (Subject Device)	TS-12140 (Predicate Device)
Outer Diameter	φ 14.8 mm	φ 12.2 mm
Inner Diameter	φ 11mm	φ 10 mm
Working Length	1320 mm	1350 mm
Total Length	1400 mm	1450 mm

MODEL: MAJ-1440(Subject Device) vs. PB-10(Predicate Device)

Specifications	MAJ-1440 (Subject Device)	PB-10 (Predicate Device)
Set Pressure of Balloon	5.4 kpa + - 2.6kpa	5.6 kpa + - 2 kpa
Power Supply	120V/230V	120V/230V
Dimensions	370(W)×242(H)×473.5(D)	300(W)×200(H)×300(D)
Weight	19.5 kg	8.7 kg

7. Materials

All the patient contact materials used in the SMALL INTESTINAL VIDEOSCOPE SYSTEM are identical to those used in the legally marketed Olympus devices.

8. Summary including conclusion drawn from non-clinical tests

When compared to the predicate devices, SMALL INTESTINAL VIDEOSCOPE SYSTEM do not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety and effectiveness. In addition, the provided clinical article and documents support the safety and efficacy of the subject system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 8 2005

Olympus Medical Systems Corporation
c/o Neil E. Devine, Jr.
Intertek Testing Services NA, Inc.
3033 Madison Avenue, SE
GRAND RAPIDS MI 49548

Re: K051551
Trade/Device Name: Small Intestine Videoscope System
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Product Code: FDA
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Product Code: KNT
Regulatory Class: II
Dated: June 10, 2005
Received: June 13, 2005

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number(if known): K051551

Device Name: **SMALL INTESTINAL VIDEOSCOPE SYSTEM**

Indications for Use:

SMALL INTESTINAL VIDEOSCOPE SYSTEM

This system is composed of the small intestinal videoscope and the other ancillary equipment. The small intestinal scope has been designed to be used with the Olympus Video System Center, light source, endoscope balloon controller, splinting tube, balloons, documentation equipment, video monitor, electrosurgical unit, endo-therapy accessories such as biopsy forceps and other ancillary equipment for endoscopy and endoscopic surgery within the upper and lower digestive tract including the esophagus, stomach, duodenum, small intestine and colon, by either oral or anal insertion.

David G. Segarson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051551

Prescription Use ✓ OR Over-The-Counter Use _____

(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)